Remarks/Arguments

Claims 1-3, 5-7, 9 and 13-15 were originally pending. Claims 4, 8, 10-12 and 16-70 were previously canceled. Claims 1-3, 5-7, 9 and 13-15 have been rejected. Claims 6 and 9 have now been canceled. Claims 1-3, 5, 7, and 13-15 are now pending. Applicants propose to amend claim 1. Applicants propose to limit the scope of claim 1 to obtaining a sample by nipple aspiration of the milk ducts or by ductal lavage of at least one breast milk duct and examining the ductal fluid sample to determine the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells, merely to move the present application towards allowance, and with no acceptance of the Examiner's position, which applicants maintain is contrary to M.P.E.P. Section 211.03. Applicants also reserve the right to pursue the subject matter in a later application. No new matter has been added by way of amendment.

Applicants ask that all pending claims be examined and allowed.

Changes to the Specification

The Examiner has suggested that the Applicants amend the first line of the specification to include the provisional application 60/117,281. The Applicants have updated the application priority information accordingly.

The Rejections Under 35 U.S.C. §102(b) Should be Withdrawn

The Examiner has maintained the rejection of claims 1-4, 8, 9, and 13-15 under 35 U.S.C. 102(b) as being anticipated by Fabian *et al.* (J. Cell Biochem., 1993, 17G: 153-160, IDS). The Examiner argues that Fabian *et al.* teaches a method of needle aspiration that would include ductal fluid (secretions) and ductal epithelial cells. Although the Applicants respectfully disagree that Fabian *et al.* teaches or suggests all the limitations of the present claims, in order to expedite prosecution, the Applicants have amended claim 1 to include the limitation of obtaining a sample by nipple aspiration of the milk ducts or by ductal lavage of at least one breast milk duct. Both ductal lavage and nipple aspiration are noninvasive methods of obtaining ductal fluid from a patient.

Since Fabian *et al.* does not teach or suggest obtaining a sample by nipple aspiration of the milk ducts or by ductal lavage of at least one breast milk duct, Fabian *et al.* cannot anticipate the claim 1 of the present invention as amended. For this reason, the Applicant's respectfully request the rejections under 35 U.S.C. 102(b), be withdrawn.

The Examiner has maintained the rejection of claims 1-6, 8, and 13-15 under 35 U.S.C. 102(b) as being anticipated by Sauter *et al.* (British J. Cancer., 1997, 76(4): 494-501, IDS). The Examiner argues that Sauter *et al.* teaches a non-invasive method for the early detection of breast cancer comprising collecting nipple aspirate fluid from a patient, cytologically analyzing the fluid (e.g. computerized image analysis of nipple aspirate fluid epithelial cells), and evaluating the promising cancer markers, wherein the patients were categorized by their risk for breast cancer as having no risk factors, a first degree relative with breast cancer, a history of curative treatment for ductal carcinoma in situ (DCIS), or invasive breast cancer, precancerous

mastopathy, atypical hyperplasia (AH) or lobular carcinoma in situ (LCIS) or recently diagnosed invasive cancer or the breast.

Although the Applicants respectfully disagree that Sauter *et al.* teaches or suggests all the limitations of the present claims, in order to expedite prosecution, the Applicants have amended claim 1 to include the limitation of obtaining a sample by nipple aspiration of the milk ducts or by ductal lavage of at least one breast milk duct and examining the ductal fluid sample to determine the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells, wherein asymptomatic patients determined to have the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer.

Since Sauter *et al.* does not teach or suggest examining a ductal fluid sample to determine the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells, wherein asymptomatic patients determined to have the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer, Sauter *et al.* cannot anticipate the claim 1 of the present invention as amended. For this reason, the Applicant's respectfully request the rejections under 35 U.S.C. 102(b), be withdrawn.

The Examiner has maintained the rejection of 1-4, 6-8, and 13-15 under 35 U.S.C. 102(b) as being anticipated by JAMA (May 7, 1973, 224 (6): 823-827). The Examiner argues that the JAMA reference discloses using the claimed method; Dr. Sartorious found carcinomas in the breast of patients who appeared asymptomatic. Although the Applicants respectfully disagree

that the JAMA reference teaches or suggests all the limitations of the present claims, in order to expedite prosecution, the Applicants have amended claim 1 to include the limitation of obtaining a sample by nipple aspiration of the milk ducts or by ductal lavage of at least one breast milk duct and examining the ductal fluid sample to determine the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells, wherein asymptomatic patients determined to have the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer. Since the JAMA reference does not teach or suggest examining a ductal fluid sample to determine the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells, wherein asymptomatic patients determined to have the presence of an estrogen receptor on precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer, the JAMA reference cannot anticipate the claim 1 of the present invention as amended. For this reason, the Applicant's respectfully request the rejections under 35 U.S.C. 102(b), be withdrawn.

The Double Patenting Rejection Should be Withdrawn

The Examiner has maintained the rejection of claims 1-3, 5-7 and 15 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 9, 13, 15, and 19-21 of USP 6,610,484. In the Applicant's response filed on December 7, 2006, the Applicants noted that the current Application 10/608,225 and USP 6,610,484 were, at the time the invention of Application 10/608,225 was made, owned by Cytyc Corporation. What the

Applicants failed to make clear is that both the current Application 10/608,225 and USP 6,610,484 claim priority from the same Provisional Application 60/117,281 filed January 26, 1999. Thus, a terminal disclaimer is not necessary. For this reason, the Applicants respectfully request the non-statutory obviousness-type double patenting rejection be withdrawn.

Claims 1, 6, 7 and 15 have been rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 2, 11, 13, and 22 of USP 6,642,009. In the Applicant's response filed on December 7, 2006, the Applicants noted that the current Application 10/608,225 and USP 6,642,009 were, at the time the invention of Application 10/608,225 was made, owned by Cytyc Corporation. What the Applicants failed to make clear is that the current Application 10/608,225 claims priority from Provisional Application 60/117,281 filed January 26, 1999 while USP 6,642,009 claims priority from Provisional Application 60/166,100 filed November 17, 1999. In this case, a rejection on the grounds of non-statutory obviousness-type double patenting based on a later filed application is improper. For this reason, the Applicants respectfully request the non-statutory obviousness-type double patenting rejection be withdrawn.

For the reason mentioned above, the Applicants respectfully request the non-statutory obviousness-type double patenting rejections be withdrawn.

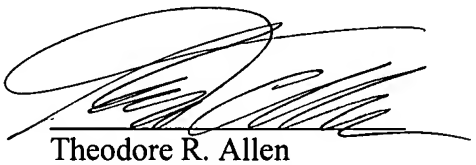
In addition, all amendments set forth above would raise no new issues that would require further consideration and/or search. Applicants submit that these amendments would place the claims into condition for allowance, or at least present the rejected claims in better form for consideration on appeal, and should therefore be entered after the final rejection under 37 C.F.R. 1.116 (a).

Conclusion

In light of the amendments and arguments presented above, Applicants respectfully submit that the claims are in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.003011 DIV.

Respectfully submitted,



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